UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCT LIABILITY LITIGATION	)	MDL NO. 2419 Master Dkt.: 1:13-md-02419-FDS

OBJECTIONS OF NON-PARTY ERLANGER HEALTH SYSTEMS, INC. TO SUBPOENA AND REQUEST TO APPEAR TELEPHONICALLY AT STATUS CONFERENCE

COMES NOW Non-Party Erlanger Health System, Inc. ("Erlanger"), having previously filed its Notice of Limited Appearance, and files its Objections to Subpoena and Request to Appear Telephonically at Status Conference, showing this Honorable Court as follows:

I. PROCEDURAL HISTORY AND BRIEF OVERVIEW

Erlanger, a hospital located in Chattanooga, Tennessee, received a *Subpoena Duces Tecum* in this case on July 17, 2013 requiring it to produce, on July 8, 2013, persons competent to testify on thirty-seven different issues and to provide documents relating to twenty-seven different categories. ("Subpoena" attached hereto as Exhibit "A"). The Subpoena contained a cover letter from Thomas Sobol, though the Subpoena was issued by J. Gerard Stranch, IV. On June 24, 2013 Erlanger's counsel sent correspondence to Mr. Sobol and Mr. Stranch containing objections to the Subpoena. ("Objections" attached hereto as Exhibit "B"). Erlanger's counsel sent Mr. Stranch and Mr. Sobol supplemental objections to the Subpoena by correspondence on June 25, 2013. ("Supplemental objections" attached hereto as Exhibit "C").[1] Both of the objections contained an invitation for Mr. Stranch and Mr. Sobol to participate in a discovery conference, pursuant to Local Rule 37.1.

[1] In accordance with Fed.R.Civ.P. 45(c), the written Objections were timely. The time specified for compliance had not yet transpired when the Objections were served and the Objections were served on the attorney designated in the Subpoena within 14 days of the service of the Subpoena.

Counsel for Erlanger spoke with Mr. Stranch on June 26, 2013 regarding the Subpoena. During that phone conference, counsel agreed that the unresolved disagreements regarding the Subpoena could be heard at the July 18, 2013 status conference. Mr. Stranch also agreed that the July 8, 2013 deposition was not going to go forward. Counsel further agreed that Plaintiffs would not be required to file a Motion to Compel (pursuant to Fed.R.Civ.P. 45(c)) and that Erlanger would not be required to file a Motion to Quash[2] in order to protect their respective rights and interests with regard to the Subpoena. Counsel for Erlanger spoke again with Mr. Stranch on July 3, 2013 about the Subpoena, but no definitive decisions have been made whether discovery should be sought of Erlanger.

With regard to the substantive issues of the Subpoena, Erlanger never received any methylprednisolone acetate, cardioplegia solution, ophthalmic solution or preservative-free saline solution[3] from New England Compounding Center ("NECC") (Affidavit of Allen Broome, Pharm. D., "Broome Aff." attached hereto as Exhibit "D", ¶ 5). Erlanger has attached a list of all medications which Erlanger purchased from NECC. (Exhibit "B" to Broome Aff.). None of the medications at issue in this lawsuit were purchased by Erlanger. Moreover, the Centers for Disease Control and Prevention created a website documenting all of the facilities which received the tainted methylprednisolone acetate and Erlanger is not on that list. (See copy of CDC website attached to Objections and attached as Exhibit "A" to Broome Aff.).

Therefore Erlanger cannot provide Plaintiffs with any information relevant to the facts or circumstances of this litigation.

[2] Objections pursuant to Fed.R.Civ.P.45(c) appear to address the document production aspect of a *subpoena duces tecum* rather than the testimonial aspect. However, counsel have agreed to address both aspects in the status conference, without the necessity of Erlanger also filing a Motion to Quash.

[3] These products were specifically identified in the Subpoena.

II. STANDARD OF REVIEW

The Court, under its MDL authority, has the power to issue foreign-district Subpoenas pursuant to 28 U.S.C. § 1407(b). United States ex rel. Pogue v. Diabetes Treatment Centers of America, Inc., 444 F.3d 462, 468 (6th Cir. 2006). When 28 U.S.C. § 1407(b) is the basis to issue a subpoena to a foreign-district non-party deponent, the MDL sits as a judge of the district court where the deponent resides. (Id.). As explained in Pogue v. Diabetes Treatment Centers of America,

> ..The MDL statute empowers an MDL judge to act as a judge of the deposition or discovery district. … A Judge presiding over an MDL case therefore can compel production by an extra-district nonparty; enforce, modify or quash a subpoena directed to an extra-district non-party; and hold an extra-district nonparty deponent in contempt, notwithstanding the non-party's physical situs in a foreign district where discovery is being conducted (footnote omitted). However, because the MDL judge is acting as a judge of the deposition or discovery district where he uses the authority outlined in Section 1407(b), appeal from the exercise of such authority lies in the circuit court embracing that deposition or discovery district.

Pogue v. Diabetes Treatment Centers of America 444 F.3d 462, 468-469. (6th Cir. 2006). (internal cits. omitted). Therefore, in this case, regarding the Subpoena issued to Erlanger, the Honorable Judge Saylor sits as a judge of the United States District Court for the Eastern District of Tennessee. Therefore, this case is governed by the precedent of the United States Sixth Circuit Court of Appeals and the Court must apply the privilege law of Tennessee. See, e.g., Palmer v. Fisher, 228 F.2d 603, 608-609 (7th Cir. 1955) (*overruled on other grounds*).

III. ARGUMENT AND CITATION OF AUTHORITY

Erlanger objects to the Subpoena in its entirety as the Subpoena failed to include the statutorily required fee with service of the Subpoena. Erlanger further objects to the Subpoena as it never received any of the relevant products from NECC and, therefore, can provide no relevant information to Plaintiffs' Steering Committee ("Steering Committee"). Erlanger further objects

to the Subpoena in its entirety as it fails to comply with this Court's June 21, 2013 Orders. Erlanger also specifically objects to most of the individual testimonial and document production requirements contained within the Subpoena on the grounds those requests are unduly burdensome, overly broad, violative of HIPAA, require production of information or documents protected by the Tennessee Safety and Quality Improvement Act and are otherwise objectionable.

A. <u>The Subpoena Should be Quashed in its Entirety for Failure to Tender Witness Attendance Fees</u>

The Steering Committee failed to provide Erlanger with the $40.00 fee required upon service of the Subpoena. Fed.R.Civ.P 45(b)(1). The plain language of Fed.R.Civ.P 45(b)(1) reads as follows:

> (b) Service.
> (1) By Whom; Tendering Fees; Serving a Copy of Certain Subpoenas. Any person who is at least 18 years old and not a party may serve a subpoena. **Serving a subpoena requires delivering a copy to the named person and, if the subpoena requires that person's attendance, tendering the fees for 1 day's attendance and the mileage allowed by law.** Fees and mileage need not be tendered when the subpoena issues on behalf of the United States or any of its officers or agencies. If the subpoena commands the production of documents, electronically stored information, or tangible things or the inspection of premises before trial, then before it is served, a notice must be served on each party.

(emphasis supplied). The Steering Committee was clearly aware of the need to supply Erlanger with the statutorily required fee. The Proof of Service attached to the Subpoena states,

> Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also tendered the witness fee for one day's attendance, and the mileage allowed by law, in the amount of
>
> $_____
>
> My fees are $_____ for travel and $____ for services, for a total of $<u>0.00</u>.

(Subpoena, page 6). As the Steering Committee failed to provide the required witness fees, the Subpoena is invalid on its face and unenforceable. This Court should quash the Subpoena for failure to tender the required fees.

B. The Subpoena Should Be Quashed In Its Entirety For Failure To Comply With This Court's Order

This Court issued an Order on Central Enforcement of Subpoenas ("Subpoena Enforcement Order") on June 21, 2013 which permits the issuance of subpoenas to non-parties. The Subpoena Enforcement Order, among other things, refers to the Steering Committee's intent to issue subpoenas to "[p]ain clinics, hospitals, and other entities or individuals who purchased NECC's methyl prednisolone acetate, cardioplegia solution or ophthalmic solution." (¶2, Subpoena Enforcement Order).[4] Erlanger never purchased or otherwise received any methylprednisolone acetate, cardioplegia solution or ophthalmic solution from NECC; therefore, the Steering Committee should never have served the Subpoena on Erlanger in the first place. (See Broome Aff.). Erlanger cannot produce any information on the products at issue because it never purchased any of those products. As Erlanger did not receive the listed products identified in the Subpoena Enforcement Order, the entire Subpoena should be quashed.

The same day the Subpoena Enforcement Order was filed, the Court issued an Order Granting Plaintiffs Leave to Serve Subpoenas and Qualified Protective Order Regarding Protection of Health Information ("QPO") which sets out an up-front process for the subpoenaed entities to produce patients' Protected Health Information. The QPO limited the timeframe for Steering Committee's subpoena to dates certain, stating:

> The information requested and produced shall be limited to the names of patients that have been identified as receiving NECC solutions, medications or compounds from January, 2011- November, 2012 the patients' last known address, the

[4] Although the Subpoena requests information concerning preservative-free saline solution (see e.g., ¶ 15, Exhibit "A" and ¶ 5, Exhibit "B" of Subpoena), this medication was not listed in the Subpoena Enforcement Order.

> records identifying that NECC was the supplier of the solution, medications or compound, including lot number, the hospital or healthcare facilities' NECC product purchase records, including order forms, prescriptions, billing and accounts receivable, the hospital or healthcare facilities' NECC product storage and patient distribution records, and any other information that lead counsel and the PSC reasonably determine necessary to the prosecution and resolution of these actions.

(QPO, page 2). Despite this clear direction from the Court, the Subpoena requests information regarding a five-year period from October 6, 2007 – October 6, 2012. (¶¶11, 12, 13, 14, 15, 16 and 17, Exhibit "A" to Subpoena; ¶¶ 1, 2, 3, 4, 5, 6, 7, Exhibit "B" To Subpoena) (See also ¶ 8, Exhibit "B" to Subpoena, which sets out a one-year time frame for information). The Subpoena should be quashed for failure to follow the clear Order of this Court and any future Subpoena should be time-limited in the information requested, pursuant to the Court's Order.

Moreover, in the QPO, the subpoenaed entities are given thirty days to produce the requested information to a HIPAA compliant vendor. In contrast to the thirty days given by this Court to non-parties to produce documents, the Erlanger Subpoena only allows Erlanger twenty-one days to respond. The Subpoena was served on June 17, 2013 and the Subpoena required that Erlanger produce documents by July 8, 2013, fewer than the thirty days given by this Court. Not only should the Subpoena be quashed for this reason, but any future subpoena should expressly allow at least thirty days to produce information, in accordance with the Court's QPO.

Additionally, the QPO requires that a copy of the Order be attached to any subpoenas issued by Plaintiffs. The Subpoena issued to non-party Erlanger did not contain a copy of the Order, as required. As with the preceding timeframe allowed by the QPO, not only should the Subpoena be quashed for not attaching the QPO, but any future subpoena should contain the QPO.

C. The Information Requested from Erlanger Is Irrelevant and Unduly Burdensome and Therefore Those Portions of the Subpoena Should be Quashed

Erlanger objects, cumulative to the preceding objections, to the following testimonial requirements contained in Exhibit "A" to the Subpoena as unduly burdensome: 1, 2, 6, 10-37.[5] Erlanger also objects, cumulative to the preceding objections, to all 27 requests for production of documents contained in Exhibit "B" to the Subpoena as unduly burdensome.

A Court is required to quash or modify a subpoena if the subpoena "subjects a person to undue burden." Fed.R.Civ.P. 45(c)(3)(A)(iv). Federal Rule of Civil Procedure 45(c), in pertinent part, states:

> (c) Protecting a Person Subject to a Subpoena.
>
> > (1) *Avoiding Undue Burden or Expense; Sanctions.* A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The issuing court must enforce this duty and impose an appropriate sanction--which may include lost earnings and reasonable attorney's fees--on a party or attorney who fails to comply.
> >
> > …
> >
> > (3) *Quashing or Modifying a Subpoena.*
> >
> > > (A) *When Required.* On timely motion, the issuing court must quash or modify a subpoena that:
> > >
> > > > (i) fails to allow a reasonable time to comply;
> > > >
> > > > (ii) requires a person who is neither a party nor a party's officer to travel more than 100 miles from where that person resides, is employed, or regularly transacts business in person--except that, subject to Rule 45(c)(3)(B)(iii), the person may be commanded to attend a trial by traveling from any such place within the state where the trial is held;
> > > >
> > > > (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
> > > >
> > > > (iv) subjects a person to undue burden.

In addition, Fed.R.Civ.P. 26(b)(2) provides, in relevant part, that:

[5] Erlanger also objects to Requests Nos. 1 and 2 on the grounds that they seek information protected by the attorney/client privilege and the work product privilege.

> [o]n motion or on its own, the court must limit the frequency or extent of discovery otherwise allowed by these rules or by local rule if it determines that …(iii) the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issue at stake in the action and the importance of the discovery in resolving the issue.

(emphasis supplied).

In the Eastern District of Tennessee, the Court evaluates undue burden by weighing the burden to the subpoenaed party against the value of the information to the party issuing the subpoena. Travelers Casualty & Surety Company of America v. Pascarella, 2011 WL 2149524 at *1 n. 1 (E.D. Tenn. May 31, 2011). (unpublished order) citing Travelers Indem. Co. v. Metropolitan Life Insurance Co. 228 F.R.D. 111, 113 (D. Conn 2005). Further, when a non-party objects to the relevancy of a request, the Court places the burden on the party seeking disclosure to show the relevancy of the requests. Travelers Casualty & Surety Company of America v. Pascarella, 2011 WL 2149524 at 2 (E.D. Tenn. May 31, 2011). In another case out of the Sixth Circuit, the court held that when determining whether an undue burden exists, such factors as relevance, the need of the [requesting] party for the documents, the breadth of the document request, the time period covered by it, the particularity with which the documents are described and the burden imposed. Musarra v. Digital Dish, Inc., CIVA 2:05-CV-545, 2008 WL 4758699 (S.D. Ohio Oct. 30, 2008) quoting American Elec. Power Co. v. United States, 191 F.R.D. 132, 136 (S.D.Ohio 1999).

There is some dispute among the courts in the Eastern District about whether the issue of burdensomeness should be addressed differently depending on whether the discovery request is directed to a non-party or a party. However, in a First Circuit case[6], Cusumano v. Microsoft Corp., the Court held that the fact that a Subpoenaed entity is a non-party to the litigation should

[6] Erlanger is mindful that the Sixth Circuit provides binding authority (See above, Standard of Review). Erlanger cites this First Circuit case as persuasive authority.

be a consideration in whether the entity is required to produce the requested information. Cusumano v. Microsoft Corp., 162 F.3d 708, 717 (1st Cir. 1998). The Cusumano Court wrote, "[i]t is also noteworthy that the respondents are strangers to the antitrust litigation; insofar as the record reflects, they have no dog in that fight. Although discovery is by definition invasive, parties to a law suit must accept its travails as a natural concomitant of modern civil litigation. Non-parties have a different set of expectations. Accordingly, concern for the unwanted burden thrust upon non-parties is a factor entitled to special weight in evaluating the balance of competing needs." (emphasis supplied) (Id. at 717).

First and foremost, now that Erlanger has objected to the Subpoena on the grounds it is unduly burdensome, the Steering Committee cannot meet its burden to establish the testimony and documents that are sought are relevant. Here, it is undisputed that Erlanger never received methylprednisolone acetate or cardioplegia solution, ophthalmic solution or preservative-free saline from NECC. (Broome Aff. ¶ 5). Therefore, Erlanger does not have any documents pertinent to resolving any of the claims of the plaintiffs who are in the MDL and all of the requested documents are irrelevant. For example[7], any request regarding Erlanger's corporate structure and/or management is completely irrelevant and Plaintiffs have little, if any, need for such documents (¶ 37 of Exhibit "A" to Subpoena, ¶¶ 22, 24, 25 and 27 of Exhibit "B" to Subpoena). For further example, the Subpoena requires Erlanger "[t]o provide testimony regarding the ownership and management of the Healthcare Provider's operations." (¶31, Exhibit "A" to Subpoena). The Subpoena also requests "[a]ny and all documents and/or ESI reflecting or containing the names, addresses and positions (President, Vice-President, Director) within the Healthcare Provider of all officers and directors of the Healthcare Provider during the calendar years 2011, 2012 2013." (¶23, Exhibit "B" to Subpoena). Additionally, the Subpoena requests

[7] These examples are intended to illustrate the reasons for the objection, and not as the exclusive list of objections.

"[a]ny and all documents showing the names of physicians and/or pharmacists that prescribed and/or dispensed NECP products to patients." (¶26, Exhibit "B" to Subpoena).[8] All of the requested documents are unduly burdensome and irrelevant as none of the plaintiffs in the MDL are or were patients at Erlanger and therefore the Subpoena should be quashed.

Not only does the Subpoena attempt to ascertain information regarding the entirety of Erlanger's business relationship with NECC, the Subpoena attempts to obtain information regarding Erlanger's relationship with other pharmacies, who are likewise non-parties to the litigation and have not been linked to any fungal meningitis outbreak. For example, the Subpoena requires Erlanger, "[t]o provide testimony regarding the procurement of MPA, or its generic or name-brand equivalent, from **any** producer, compounding facility, or manufacturer other than NECP, during the five-year period immediately preceding October 6, 2012 …" (emphasis supplied). (¶12, Exhibit "A" to Subpoena). The information requested regarding Erlanger's purchases from non-parties to this litigation is wholly irrelevant to the Steering Committee's claims in this MDL. In addition, it is unduly burdensome for Erlanger to have to provide the Steering Committee such information. Moreover, the request requires Erlanger to produce information for an arbitrary-five year period, outside the scope of the January, 2011-November, 2012 time-frame in the QPO, as discussed above.

Given the undue burden that would be placed on Erlanger to comply with the Subpoena, especially in light of its status as a non-party, weighed against the Plaintiff's minimal (if any) need for the documents, the Subpoena should be quashed as unduly burdensome on Erlanger.

[8] At Erlanger, the only way to identify the particular physician(s) who prescribed a particular medication is by reading through each of the medical charts of every patient who received that medication to determine which physician prescribed it. It would be very burdensome and expensive for Erlanger to identify the names of individual physicians who prescribed certain medications. (¶ 8, Broome Aff.).

D. The Information Requested from Erlanger Should be Deemed Overly Broad and The Overly Broad Portions Should Be Quashed

The Courts have routinely held that a Subpoena can be quashed or modified if the information requested is overly broad. Erlanger objects, cumulative to the preceding objections, to the following testimonial requirements contained in Exhibit "A" to the Subpoena as overly broad: 1, 2, 6 and 10 - 37. Erlanger also objects, cumulative to the preceding objections, to all 27 requests for production of documents contained in Exhibit "B" to the Subpoena as overly broad.

As Erlanger did not receive any of the medications or products in dispute, the remaining information requested from Erlanger is overly broad. In an analogous case, the Court quashed portions of subpoenas to two non-parties as the information sought was overly broad. Viking Yacht Co. v. Composites One LLC, 3:07-MC-001, 2007 WL 869623 (E.D. Tenn. Mar. 21, 2007). In Viking, the plaintiffs served several non-parties, including Skier's Choice, Inc. and MasterCraft Boat Company with *subpoenas duces tecum*, requesting documents regarding these non-parties' use and experience with specific gel coats used on boats. In the underlying litigation, the plaintiffs alleged that defendant's gel coats were defective. Plaintiffs sought information from non-parties about the non-parties' use and experience with defendant's gel coats, including information concerning the non-parties communications with defendant regarding problems with the gel coats. The non-parties did not produce the information requested and plaintiffs filed a motion to compel. The non-parties objected, arguing that the information sought was, *inter alia*, overly-broad. The non-parties objection was premised on the fact that they did not use the specific unique gel coats at issue in the litigation, though they had used other gel coats from defendant. The court found that much of the information sought was

overly broad as it sought information regarding any and all gel coats used at any time by the non-parties, not just the gel coats at issue in the underlying case. (Id.).

The Viking case is parallel to the situation we have in this case. Here, the Steering Committee is attempting to obtain information regarding all medications purchased by non-party Erlanger, including medications that were not created or supplied by NECP. The Steering Committee's Subpoena requests information far beyond what is at issue in the underlying lawsuit. Therefore, the Subpoena should be quashed for its over-breadth.[9]

Despite the fact that Erlanger did not receive any of the relevant from NECC, the Subpoena requires Erlanger to produce a list of all of the patients who received *any* products from NECC. Erlanger specifically objects to Subpoena Request Nos. 17 and 18 from Exhibit "A" and 7 and 8 from Exhibit "B" which require the production of and testimony regarding the names and information all patients who received NECC product during a specified period. Again, as Erlanger understands it, this litigation does not involve every drug or product produced by NECC.[10] Therefore, the requirement that Erlanger produce information regarding every

[9] In a First Circuit case, Heidelberg v. Tokyo, there was a very similar result. In Hiedelberg, the Court quashed a non-party subpoena which was determined to be overly broad. Heidelberg Americans, Inc. v. Tokyo Kikai Seisakusho, Ltd. et al., 333 F.3d 38 (1st Cir. 2003). In Heidelberg, Defendants Tokyo Kikai Seisakusho and TKS (collectively "TKS") served a subpoena on non-party Heidelberg seeking documents pertaining to Heidelberg's previous acquisition discussions with the Plaintiff, Goss Graphic Systems, Inc. ("Goss"). Heidelberg had previously discussed acquiring Goss, but had ultimately decided not to pursue the acquisition. Years later, Goss brought suit against TKS alleging TKS' unfair business practices, including illegal dumping, contributed to Goss' financial woes and eventual bankruptcy. TKS' defense was that it was Goss' inept management that led to Goss' financial situation, not TKS' business practices. TKS subpoenaed non-party Heidelberg attempting to obtain documents to show that Heidelberg decided not to acquire Goss because of Goss' inept management. Heidelberg filed a Motion to Quash the Subpoena which was granted by the trial court. TKS appealed and the Court of Appeals affirmed. The Court of Appeals found that the documents requested, even if relevant, were not probative of the central issue in the case: whether TKS engaged in illegal dumping or business practices which harmed Goss. The Court found that the materials requested were, *inter alia*, overly broad and not reasonably calculated to lead to the discovery of admissible evidence. The Court also weighed the burden on the non-party to produce the document and found it was an undue burden on Heidelberg to produce the documents. (Id at 41-42).

[10] Erlanger is mindful of the broad language accorded the Steering Committee in the QPO to issue Subpoenas (QPO, p. 5). However, the Subpoena Enforcement Order lists the pertinent NECC medications the Steering Committee intends to be the subject of the subpoenas as methylprednisolone acetate, cardioplegia solution and ophthalmic solution, rather than any NECC product. Having specified the medications at issue in the Subpoena Enforcement

patient who may have or did receive any NECC product, is overly broad. Even more egregious, the Subpoena requests information which has nothing to do with any drugs or product purchased by Erlanger from NECC. For example, ¶ 23 from Exhibit "B", which was previously discussed as being unduly burdensome, is also overly broad. That request requires Erlanger to produce "any and all documents and/or ESI [Electronically Stored Information] containing the names and positions (President, Vice-President, Director, etc.) within the Healthcare Provider of all officer and directors of the Healthcare Provider during the calendar years 2011, 2012 and 2013." (¶ 23, Exhibit "B" to Subpoena). Such a request is overly broad as it has nothing to do with any of the issues in this litigation. Erlanger should not be forced to provide every document over a three-year period that contained the names of all of its directors and officers. It would be virtually impossible for Erlanger to find every such document that exists from that time period and, even if it could produce all such documents, the request has nothing to do with the central issue (or any issue) in this litigation; therefore Requests No. 23 should be stricken from the Subpoena as overly broad. Additionally, the Subpoena requests Erlanger "[t]o provide testimony regarding the ownership and management of the Healthcare Provider's operations" (¶ 31, Exhibit "A" to Subpoena), and the relationship between Erlanger and Chattanooga-Hamilton Hospital Authority (¶ 37, Exhibit "A" to Subpoena). Once again, Erlanger's corporate structure, ownership and management have nothing to do with the MDL litigation and, therefore, Request Nos. 31 and 37 of Exhibit "A" should be stricken from the Subpoena as overly broad. Likewise, Request Nos. 22, 24, 25, and 27 of Exhibit "B" should be stricken from the Subpoena as overly broad.

In addition, the Subpoena requires Erlanger to provide testimony regarding several Tennessee Rules and Regulations which have nothing to do with this litigation and,

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Order, the Steering Committee should not be permitted to seek subpoena enforcement regarding medications not specified in the Subpoena Enforcement Order.

consequently, are overly broad. Specifically, the Subpoena requires Erlanger to produce someone competent to testify regarding the Health Provider's compliance with Tenn. Comp. R. & Regs. R. § 1140-01-.08. (¶27, Exhibit "A" to Subpoena). Tenn. Comp. R. & Regs. R. § 1140-01-.08 is a Tennessee regulation which regulates applications for a license to operate as a pharmacy practice site, manufacturer or wholesaler. Erlanger's ability to operate a pharmacy practice site, manufacturer or wholesaler is not an issue in this case nor is it relevant to any of the pending claims in the MDL. Erlanger is simply a healthcare facility that purchased some NECC product and it should not be forced to provide documents regarding its compliance with a statute that has nothing to do with the allegations in the MDL. Similarly, the Subpoena requires Erlanger to provide testimony regarding Tenn. Comp. R. & Regs. R. § 1140-01-.04. (¶28, Exhibit "A" to Subpoena), which is a regulation regarding pharmacy internships. Erlanger's employees' applications for a pharmacy internship license have no relevance to pending litigation concerning NECC's allegedly contaminated drugs. Again, Erlanger is not a defendant in the MDL action and there are no accusations that Erlanger's pharmacy staff was somehow inadequately or improperly licensed. In addition, the Subpoena requires Erlanger to provide testimony regarding Tenn. Comp. R. & Regs. R. § 1140-01-.05 which is a statute governing pharmacy licensing exams. (¶29, Exhibit "A" to Subpoena). Once again, Erlanger's pharmacists' licensing examinations have absolutely nothing to do with the pending litigation. There are no allegations in the MDL cases regarding the fitness, or lack thereof, of Erlanger's pharmacists to perform their duties and the information sought in the Subpoena is patently overly broad. All of the Subpoenaed testimony and documents concerning Tennessee Rules and Regulations are overly broad and the Subpoena's requests should be quashed.

The Steering Committee's Subpoena also requires that Erlanger, a non-party, provide liability insurance information. The Subpoena requires Erlanger, "[t]o provide testimony regarding policies of insurance, including without limitation of the foregoing, professional liability, malpractice, products liability, general liability, and comprehensive or umbrella policies, issued to the Healthcare Provider and/or its principal officers and directors and/or any physician working for or on behalf of the Healthcare Provider, for the policy periods including calendar years 2011, 2012 and 2013." (¶ 30, Exhibit "A" to Subpoena). In addition, the Subpoena requires Erlanger to produce,"[a]ny and all policies of insurance, including without limitation of the foregoing, professional liability, malpractice, products liability, general liability and comprehensive or umbrella policies, issued to Healthcare Provider and/or its principal officers and directors and/or any physician working for or on behalf of the Healthcare Provider, for the policy periods including calendar years 2011, 2012 and 2013." (¶ 21, Exhibit "B" to Subpoena). Requesting that non-party Erlanger produce a person that can testify regarding all of Erlanger's insurance policies and the insurance of all of the physicians working for it for a three-year period and to also produce all of the documents regarding each of the policies is overly broad. Neither the insurance coverage of Erlanger nor any of its physicians are at issue in this case. Therefore, Request for Production No. 21 and Testimonial Request No. 32 are overly broad and should be stricken from the Subpoena.

E. <u>The Documents Can be Obtained From Other Sources</u>

Many of the documents requested in the Subpoena can be obtained from other, more appropriate sources. For example, the Subpoena requires Erlanger "[t]o provide testimony regarding marketing information from NECP, NECP's agents, or any sales company or person marketing, selling or attempting to sell products on behalf of NECP. (¶23, Exhibit "A" to

Subpoena). Any information regarding NECC and or their sales and marketing team can and should come directly from NECC, who is a party to this litigation. Similarly, the Subpoena requires Erlanger to produce "[a]ny and all documents and/or ESI reflecting or containing marketing information from NECP, NECP's agents, or any sales company or person marketing, selling, or attempting to sell products on behalf of NECP." (¶13, Exhibit "B" to Subpoena). If Plaintiffs wish to obtain documents concerning any of NECC's sales agents, Plaintiffs should Subpoena the sales agents or NECC, both of which would be much more appropriate than requesting such information from a non-party. Therefore, the requests in Exhibit "A" and "B" of the Subpoena should be quashed.

F. The Protected Health Information Sought By Plaintiffs Is Protected By HIPAA And Therefore Erlanger Should Not Be Required To Produce Such Information

Much of the information requested by Plaintiffs is Protected Health Information and Erlanger cannot provide the requested information or else it would be in violation of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 45 C.F.R. § 164.501 *et seq*. HIPAA requires a covered entity, such as Erlanger, to keep patients' Protected Health Information confidential and not disclose that information to a third-party except under specific circumstances.

The QPO specifically states that "[t]he information requested and produced shall be limited to the names of patients that have been identified as receiving NECC solutions …" (QPO, p. 2). Erlanger cannot certify that a particular adult patient received NECC product because there was more than one vendor for the certain medications that were also supplied for a period of time by NECC. (See, Broome Aff.)[11].

[11] Using Total Parenteral Nutrition ("TPN") as an example, TPN is a medication which is comprised of several component medications and there was not a sole vendor at Erlanger for the component medications used in its TPN at the pertinent time. Some of the TPN used may have contained NECC product and some may not. (¶ 6,

Since there is no way to differentiate which adult patients were administered medications specifically from NECC and which adult patients were not, Erlanger should not be forced to produce such a list. If Erlanger produced Protected Health Information of patients who did not receive NECC product, Erlanger would be outside the protection of the QPO and would violate those individual patients' HIPAA rights. For each of these reasons, Erlanger objects to the testimonial requirements contained in Requests 17 and 18 in Exhibit "A" to the Subpoena as giving testimony regarding such topics would be outside of the QPO and would violate HIPAA. Erlanger also objects to request for production of documents No. 7 and No. 8 in Exhibit "B" to the Subpoena as producing the required documents would fall outside of the QPO and would violate HIPAA. Those requests should be stricken from the Subpoena.

G. The Portion of the Subpoena Requesting Information Protected by The Tennessee Patient Safety and Quality Improvement Act Should be Quashed

Some of the information sought by Plaintiffs in Testimonial Request No. 26 on Exhibit "A" and Request No. 17 on Exhibit "B" is protected by the Tennessee Patient Safety & Quality Improvement Act of 2011 which protects proceedings, documents and activities related to peer review and quality improvement from discovery in litigation. Specifically, Request No. 26 requires Erlanger "[t]o provide testimony regarding any investigation or inquire the Healthcare Provider performed related to NECP's compliance with UPS [sic] 797." In addition, Request No. 17 requires Erlanger to produce "[a]ny and all documents regarding any investigation or inquiry the Healthcare Provider performed related to NECP's compliance with UPS [sic] 797."

Broome Aff.). Erlanger cannot identify which adult patients received TPN with NECC-specific product and which patients received TPN that did not contain NECC product. (¶ 6, Broome Aff.). Therefore, forcing Erlanger to disclose the Protected Health Information of all of the patients who received TPN would inherently likely require Erlanger to produce the Protected Health Information of patients who did not receive any product from NECC. Likewise, with respect to methocarbomal, sodium phosphate, phytonadione, sodium acetate and potassium chloride that Erlanger purchased from NECC, Erlanger had more than one vendor. (¶ 7, Broome Aff.). Therefore, Erlanger is unable to determine if the adult patients in fact received the medication that was provided by NECC or whether the medication came from a vendor other than NECC. (Id).

As part of Tennessee's public policy, peer review and quality improvement records, testimony, statements and documents are given special protection from being disclosed outside of the quality improvement committee. The pertinent portion of the statute, Tenn. Code Ann. § 68-11-272 (c)(1), reads as follows:

> Records of a QIC [Quality Improvement Committee] and testimony or statements by a healthcare organization's officers, directors, trustees, healthcare providers, administrative staff, employees or other committee members or attendees relating to activities of the QIC shall be confidential and privileged and **shall be protected from direct or indirect means of discovery, subpoena or admission into evidence in any judicial or administrative proceeding**. Any person who supplies information, testifies or makes statements as part of a QIC may not be required to provide information as to the information, testimony or statements provided to or made before such a committee or opinions formed by such person as a result of committee participation.

(emphasis supplied). The statute makes it clear that all quality improvement documents and testimony are protected even if the materials are subpoenaed by a party in a civil action. Therefore, Erlanger objects to providing any information regarding peer review or quality improvement on the grounds that such information is privileged and confidential. The portions of the Subpoena which request peer review of quality improvement information should be quashed as protected by the Tenn. Code Ann. § 68-11-272.

H. Plaintiffs' Subpoena Amounts To Little More Than An Attempt To Obtain Additional Clients

Many of the Steering Committee's Requests for Production appear to be little more than an attempt to add clients. For example, the Subpoena requires Erlanger to produce "[s]ufficient documents to identify the name, address, phone number, and social security number of any patient that received any product manufactured by NECP from 2011- 2012 and sufficient documents to identify the specific NECP product received by the patient." (¶ 8, Exhibit "B" to Subpoena.). Additionally, the Subpoena requires Erlanger to produce a person "[t]o provide testimony regarding the identification of each and every patient that was administered an NECP

product during the five-year period immediately preceding October 6, 2012, including patient names, address, date of birth and identification of product administered". (¶ 17, Exhibit "A" to Subpoena.). The Steering Committee's attempts to fish for potential clients are completely unrelated to their duties of representation in the MDL. Their requests are also unduly burdensome to non-party Erlanger. The Steering Committee does not represent a class of all patients who received any NECC medication. Requiring Erlanger to provide Protected Health Information of patients not in this MDL is nothing more than a fishing expedition and that portion of the Subpoena should be quashed.

IV. LIST OF INDIVIDUAL OBJECTIONS

Erlanger hereby incorporates by reference all of the individual objections to each portion of the Subpoena contained in its previously-served Objections, attached hereto as Exhibits "B" and "C".

V. REQUEST TO APPEAR AT STATUS CONFERENCE TELEPHONICALLY

Counsel for Erlanger is located in Chattanooga, Tennessee. It would be expensive and difficult for counsel for Erlanger to travel to Boston, Massachusetts for the July 18, 2013 status conference. As such, Erlanger requests that their counsel be allowed to appear at the status conference telephonically and for the Court to hear Erlanger's objections to the Subpoena at that time.

VI. CONCLUSION

For all the above-stated reasons, Erlanger respectfully requests this Court inquire into Erlanger's Non-Party Objections to Subpoena and Request to Appear Telephonically at Status Conference, including the exhibits therein, and grant the relief requested by Erlanger.

Respectfully submitted this 8th day of July, 2013.

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CERTIFICATE OF SERVICE

I hereby certify that on July 8, 2013, the foregoing document, filed through the ECF system, will be sent electronically to the registered participants identified on the Notice of Electronic Filing, and paper copies will be served via U.S. Mail, postage pre-paid, to those indicated as non-registered participants.

/S/ John B. Bennett
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CERTIFICATE OF COMPLIANCE WITH RULE 37.1

Counsel for Erlanger spoke to counsel for Plaintiffs, J. Gerard Stranch IV on June 26, 2013 regarding the Subpoena. Counsel for Erlanger requested that Plaintiffs withdraw the Subpoena as Erlanger did not receive any of the relevant medications. Mr. Stranch denied the request to withdraw the Subpoena. Mr. Stranch agreed that the July 8, 2013 deposition would not move forward. Mr. Stranch also agreed that the objections to the Subpoena would be heard at the July 18th status conference. Counsel for Erlanger agreed that Mr. Stranch would not be required to file a Motion to Compel to assert Plaintiffs' rights to the information. Mr. Stranch agreed that Erlanger would not be required to file a Motion to Quash to assert or maintain its rights. Mr. Stranch and Counsel for Erlanger spoke again on July 3, 2013 about the Subpoena, but no definitive decisions have been made whether discovery should be sought of Erlanger. All of Erlanger's specific objections are attached hereto as Exhibits "B" and "C" and incorporated herein by reference. Exhibits B and C specifically identify each contested issue.

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